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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,628	03/01/2004	Benjamin G. Davis	GC571-2-C1	3111

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Genencor International, Inc.
925 Page Mill Road
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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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01/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,628	Applicant(s) DAVIS ET AL.	
	Examiner MD. YOUNUS MEAH	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-10, 19-23, 25, 26, 32-40, 44-47, 56-60, 62, 63, 69, 70, 72 and 73 is/are pending in the application.
- 4a) Of the above claim(s) 37-40, 44-47, 56-60, 62, 63 and 69-70, 72-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10, 19-23, 25, 26 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-5, 8-10, 19-23, 25-26, 32-40, 44-47, 56-60, 62-63, 69-70 and 72-73 are pending. With supplemental amendment of this application, the applicant, on dates 09/19/08 amended claims 1, 9-10, 20-23, 25-26, 32-36 and canceled claims 6, 7, 11-18, 24, 27-31, 41-43, 48-55, 61, 64-68 and 74-45. Claims 37-40, 44-47, 56-60, 62-63, 69-70 and 72-73 remain withdrawn. Claims 1-5, 8-10, 19-23, 25-26 and 32-36 are for examination.

Claim Rejections

35 U.S.C 112

2nd paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5, 8 and 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5, the recitation of the phrase "near a subsite" renders the claim indefinite because it is relative term.

Claims 33 is indefinite in the recitation of "lectin" as there is no antecedent basis for lectin in claim 1, from which this claim depends.

35 U.S.C 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed *subtillsin-type* serine hydrolase comprising proteins by **incorporation by reference** to GENE BANK Accession Numbers. These are improper incorporations by reference (see MPEP 608.01(p) (c)). Since the accession numbers in these claims are considered essential and GENE BANK is not a US patent or patent publication **incorporation by reference** to GENE BANK Accession Numbers is improper. Therefore the specification lacks the description of essential material. Given this lack of description of essential material encompassed by the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention. Therefore one of skill in the art would not recognize from the disclosure that applicants' were in possession of the claimed invention. Applicants' are referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

CLAIM Rejection - 35 U.S.C 102

35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 8, 19-23, 25-26, 32-34 and 36 are rejected under 35 U.S.C. 102(a) as being anticipated by Davis, et al. (J. org. chem. 19998, pp 9614-9615).

Davis et al. teach *B. subtilisin* protease conjugated to carbohydrate such as mannose wherein cystine residue is introduced to S1 subsite by substitution (page 9614, column 2, 2nd parg) at a preselected position enabling the highly reactive thiol group to react with an activated carbohydrate moiety (page 9614, column 2 parg. 1). Enzyme conjugate comprising said protease conjugated to carbohydrate comprise binding ability to lectin, like conA and ability to cleave lectin molecule by protease domain. It is well known in the art that carbohydrate bind lectin, such as concanavalin A (conA), selectin and other cell surface carbohydrate binding proteins, including blood (blood comprise selectin) stain (soil) (see Wang et al. JBC 1975, 250, 1490-1502). ConA and other lectins are involved in the interaction of cell surface receptor and other ligands comprising glycoprotein (Wang et al. page 1490). It is well known in the art that subtilisins are broad specificity serine proteases and would be expected to cleave a

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peptide bond in a target protein such as lectins or selectin (see Wang et al page 1491, column 1, subtilisin protease cleave conA).

CLAIM Rejection - 35 U.S.C 103a

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (J. org. chem. 19998, pp 9614-9615)., in view of Nilsson et al (Glycoconjugate 1998, 219-223).

Davis et al. teach *B. subtilisin* protease conjugated to carbohydrate such as mannose wherein cystine residue is introduced to S1 subsite by substitution (page 9614, column 2, 2nd parg) at a pre-selected position enabling the highly reactive thiol group to react with an activated carbohydrate moiety (page 9614, column 2 parg. 1). However Davis et al. do not teach said mannoside as thioethyl mannoside.

Nilsson et al teach the use of thioethyl glycoside as building block in carbohydrate synthesis. Nilsson et al teach also teach the advantage of thioglycoside, such stable under most reaction condition, can be activated easily (page 219 1st parg.) Therefore, one knowledgeable in prior art is motivated to make chimeric protein comprising *B. subtilisin* protease conjugated to mannose via thioethyl mannoside.

As such it would have been obvious to one of ordinary skill in the art to use thioethyl mannoside to conjugate *B. subtilisin* type protease as taught by Davis et al.

Conclusion

Claims 1-5, 8-10, 19-23, 25-26.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NASHAAT T NASHED can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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